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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/601,479	08/03/2000	DANETTE ANDREA DUDLEY	5712-01-MJA	5967

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EXAMINER
BALASUBRAMANIAN, VENKATARAMAN

ART UNIT	PAPER NUMBER
1624	7

DATE MAILED: 01/29/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/601,479

Applicant(s)

DUDLEY ET AL.

Examiner

Venkataraman Balasubramanian

Art Unit

1624

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 05 February 2002.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims-**

- 4) ☒ Claim(s) 1-30 is/are pending in the application.
- 4a) Of the above claim(s) 14-30 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 11-13 is/are allowed.
- 6) ☒ Claim(s) 1-10 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 2.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Election/Restrictions***

Applicant's election without traverse of Group I, claims 1-13, wherein F is N or N-CH<sub>3</sub> and X<sup>1</sup>, X<sup>2</sup>, X<sup>3</sup>, and X<sup>4</sup> are carbons in Paper No. 6 is acknowledged.

Claims 1-13 will be examined to the extent they embrace the elected subject matter.

Claims 14-30 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected subject matter.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Following reasons apply. Any claim not specifically rejected is rejected as being dependent on a rejected claim.

1. Recitation of the term "prodrug" in claims 1-4, is deemed as indefinite for more than one reason. Prodrugs in general and as noted in specification, are compounds, which undergo in vivo hydrolysis to parent active drugs. In that sense recitation of prodrugs is acceptable and would include esters, amides, alkoxycarbonyl etc. However, claim 1-4 also recites in addition to prodrugs, esters, amides which are by definition included in prodrugs. In addition, the definition of various variable groups include such groups, namely esters,

alkoxycabonyl etc. and therefore it is not clear what is the difference between these variable groups and the prodrug groups.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1,2 are rejected under 35 U.S.C. 102(b) as being anticipated by Muller et al. US 4,329,347.

Muller et al teaches several structurally analogous compounds for use as cardiotonics and antithrombotics. See formula I on col. 1 and note the definition of various variable groups. See col. 2, method A wherein Muller discloses compound of formula II, which is also claimed in the instant claims. Example 1, on col. 7 for the said compound.

Claims 1,2 are rejected under 35 U.S.C. 102(b) as being anticipated by Nishi et al. US 4,298,739.

Nishi et al teaches several carbostyryl compounds for treating several diseases including asthma inflammation, thrombus formation etc. See formula I on col. 1 and note the definition of various variable groups. Note when instant K, J, G are absent, the parent carbostyryl compounds are also taught in the reference. See col. 3-6 for several species and examples 1-473 on col. 26 through col. 100 for compounds made which include compounds claimed in the instant claims

Claims 1,2 are rejected under 35 U.S.C. 102(b) as being anticipated by Nakagawa et al. US 4,298,739.

Nakagawa et al teaches several carbostyryl compounds for treating platelet aggregation. See formula I on col. 1 and note the definition of various variable groups. Particularly note the second and third choices of B include compounds claimed in the instant claims. Note when instant K, J, G are absent, the parent carbostyryl compounds are also taught in the reference. See examples 1-435 on col. 17 through col. 58 for compounds made which include compounds claimed in the instant claims

Claims 1,2 are rejected under 35 U.S.C. 102(b) as being anticipated by Nishi et al. US 4,435,404.

Nishi et al teaches several carbostyryl compounds for treating thrombosis and embolism. See formula I on col. 2 and note the definition of various variable groups. Note when instant K, J, G are absent, the parent carbostyryl compounds are also taught in the reference. See col. 6-19 for several species disclosed and examples 1-280 on col. 46 through col. 76 for compounds made which include compounds claimed in the instant claims.

Claims 1,2 are rejected under 35 U.S.C. 102(b) as being anticipated by Richter Beilstein Handbuch der Organischen Chemie 4, Aufl. 1 EW 20-22, 1935.

See page 293 and 267.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

Art Unit: 1624

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-2 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nishi et al. US 4,298,739.

Teachings of Nishi et al. US 4,298,739, as discussed in the above 102 rejection is incorporated herein. As noted above, Nishi et al teaches several carbostyryl compounds for treating several diseases including asthma inflammation, thrombus formation etc.

Instant claims differ in requiring variously substituted quinolone compounds including the aryl ring, side chain L and the nitrogen of quinolone.

As seen, Nishi et al permits various substituents in the carbostyryl but exemplifies not all of them.

However, Nishi et al. teaches the equivalency of exemplified substituted carbostyryl in the examples 1-473 taught with those claimed therein. See formula I on

col. 1 and note the definition of various variable groups. Thus, it would have been obvious to one having ordinary skill in the art at the time of the invention was made would have been to make compounds variously substituted in carbostyryl ring as permitted by the reference and expect resulting compounds (instant compounds) to possess the uses taught by the art in view of the equivalency teaching outline above.

Claims 1-2 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nakagawa et al. US 4,298,739.

Teachings of Nakagawa et al. US 4,298,739, as discussed in the above 102 rejection is incorporated herein. As noted above, Nakagawa et al teaches several carbostyryl compounds for treating platelet aggregation.

Instant claims differ in requiring variously substituted quinolone compounds including the aryl ring, side chain L and the nitrogen of quinolone.

As seen, Nakagawa et al permits various substituents in the carbostyryl but exemplifies not all of them.

However, Nakagawa et al. teaches the equivalency of exemplified substituted carbostyryl in the examples 1-435 taught with those claimed therein. See formula I on col. 1 and note the definition of various variable groups. Thus, it would have been obvious to one having ordinary skill in the art at the time of the invention was made would have been to make compounds variously substituted in carbostyryl ring as permitted by the reference and expect resulting compounds (instant compounds) to possess the uses taught by the art in view of the equivalency teaching outline above.

Claims 1-2 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nishi et al. US 4,435,404.

Teachings of Nishi et al. US 4,298,739, as discussed in the above 102 rejection is incorporated herein. As noted above, Nishi et al teaches several carbostyryl compounds for treating thrombosis and embolism.

Instant claims differ in requiring variously substituted quinolone compounds including the aryl ring, side chain L and the nitrogen of quinolone.

As seen, Nishi et al permits various substituents in the carbostyryl but exemplifies not all of them.

However, Nishi et al. teaches the equivalency of exemplified substituted carbostyryl in the examples 1-280 taught with those claimed therein. See formula I on col. 2 and note the definition of various variable groups. Thus, it would have been obvious to one having ordinary skill in the art at the time of the invention was made would have been to make compounds variously substituted in carbostyryl ring as permitted by the reference and expect resulting compounds (instant compounds) to possess the uses taught by the art in view of the equivalency teaching outline above.

***Allowable Subject Matter***

Claims 11-13 are allowable barring uncovering of any new prior art in a subsequent search. Said claims are deemed allowable as the specific species embraced in these claims are not taught in the prior art of record.



References cited in the Information Disclosure Statement (paper #2) are made of record except for the International Search Report, which is not a publication per se and thus is not properly cited as such in the IDS. See MPEP 2205.

### **Conclusion**

Any inquiry concerning this communication from the examiner should be addressed to Venkataraman Balasubramanian (Bala) whose telephone number is (703) 305-1674. The examiner can normally be reached on Monday through Thursday from 8.00 AM to 6.00 PM. The Supervisory Patent Examiner (SPE) of the art unit 1624 is Mukund Shah whose telephone number is (703) 308-4716.

The fax phone number for the organization where this application or proceeding is assigned (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

  
Venkataraman Balasubramanian

1/24/2003